

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/821,229
Filing Date: April 8, 2004
Applicant(s): Tara Ziolo et al.
Group Art Unit: 3733
Examiner: Steven J. Cotroneo
Title: BONE FIXATION DEVICE
Attorney Docket: 5490E-000365

Director of the United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.131

Sir:

I hereby declare under penalty of perjury as follows:

1. That I am one of the inventors of the above-identified application.
2. That the invention was conceived and reduced to practice in this country prior to September 3, 2003—the filing date of United States Publication No. 2005/0049593 to Duong.

3. That the redacted engineering drawings of Exhibit A illustrate the various components of the subject invention that were produced by an in-house manufacturing facility of the assignee and shown to work for their intended purpose prior to September 3, 2003—the filing date of United States Publication No. 2005/0049593 to Duong.

4. The components described above in Section 3 and shown in Exhibit A were tested and shown to function such that cooperation between a first cam of a fastener shaft and a second cam of an annular member resulted in expansion of the annular member in a radial direction from an unexpanded position to an expanded position when the fastener shaft was rotated relative to the annular member. Prior to such rotation, the fastener shaft and annular member were able to freely rotate about an axis of the fastener shaft and collectively seat in a fixation hole of a bone fixation plate at various angles relative to the fixation plate. When the fastener shaft was rotated relative to the annular member to cause the annular member to expand in a radial direction, such expansion prevented the fastener shaft and annular member from backing out of the fixation hole.

5. That each of the redacted drawings of Exhibit A bears a date prior to September 3, 2003.

6. That the invention has never been abandoned, suppressed, or concealed.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are being made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, and patent issuing thereon, or any patent to which this verified statement is directed.

Dated: 5/27/10



Rui Ferreira

Dated: 5/19/10

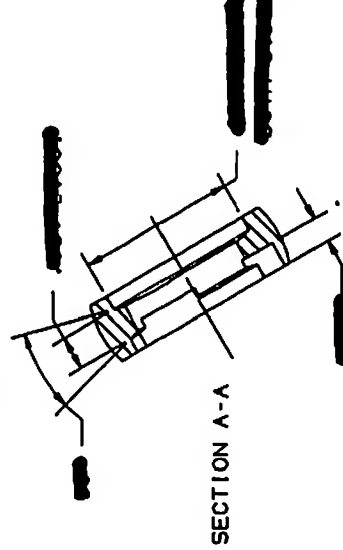


Tara Ziolo

15379297.1

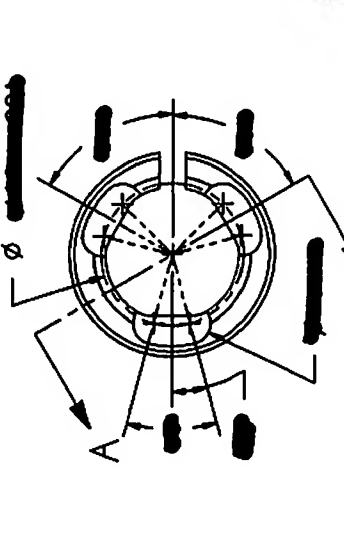
EXHIBIT A

APPROVALS MAINTAINED ELECTRONICALLY WITHIN AGILE SYSTEM				REVISIONS			
REV	EN NO.	DCR/ECR No.	DESCRIPTION	DRAFT	DATE	APPROVED	
A			INITIAL PROTOTYPE RELEASE	JTC			



SECTION A-A

MANUFACTURING



PART NO.
RD-3753

NOTES:

1 ALL MACHINED SURFACES TO HAVE A SURFACE FINISH OF $\sqrt{\text{ }}$ OR SMOOTHER UNLESS OTHERWISE SPECIFIED

2 BEAD BLAST PER SPEC #741019

3 PASSIVATE PER SPEC #741000

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LIST OF MATERIALS

QTY	PART NUMBER	NOMENCLATURE OR DESCRIPTION	REMARKS	ITEM
UNLESS OTHERWISE SPECIFIED				
DIMENSIONS ARE IN INCHES				
TOLERANCES:				
2 PLACE DECIMALS $\pm .01$				
3 PLACE DECIMALS $\pm .005$				
FRACTIONS $\pm 1/64$				
ANGLES $\pm 1^\circ$				
MATERIAL				
T16A14V				
FINISH				
$\sqrt{\text{ }}$				
HARDNESS				
NEXT ASSY				

TRI-CAM PROTOTYPE BUSHING

FIRST USED ON: [REDACTED] SIZE: B

USED ON: [REDACTED] PROJ NO: [REDACTED]

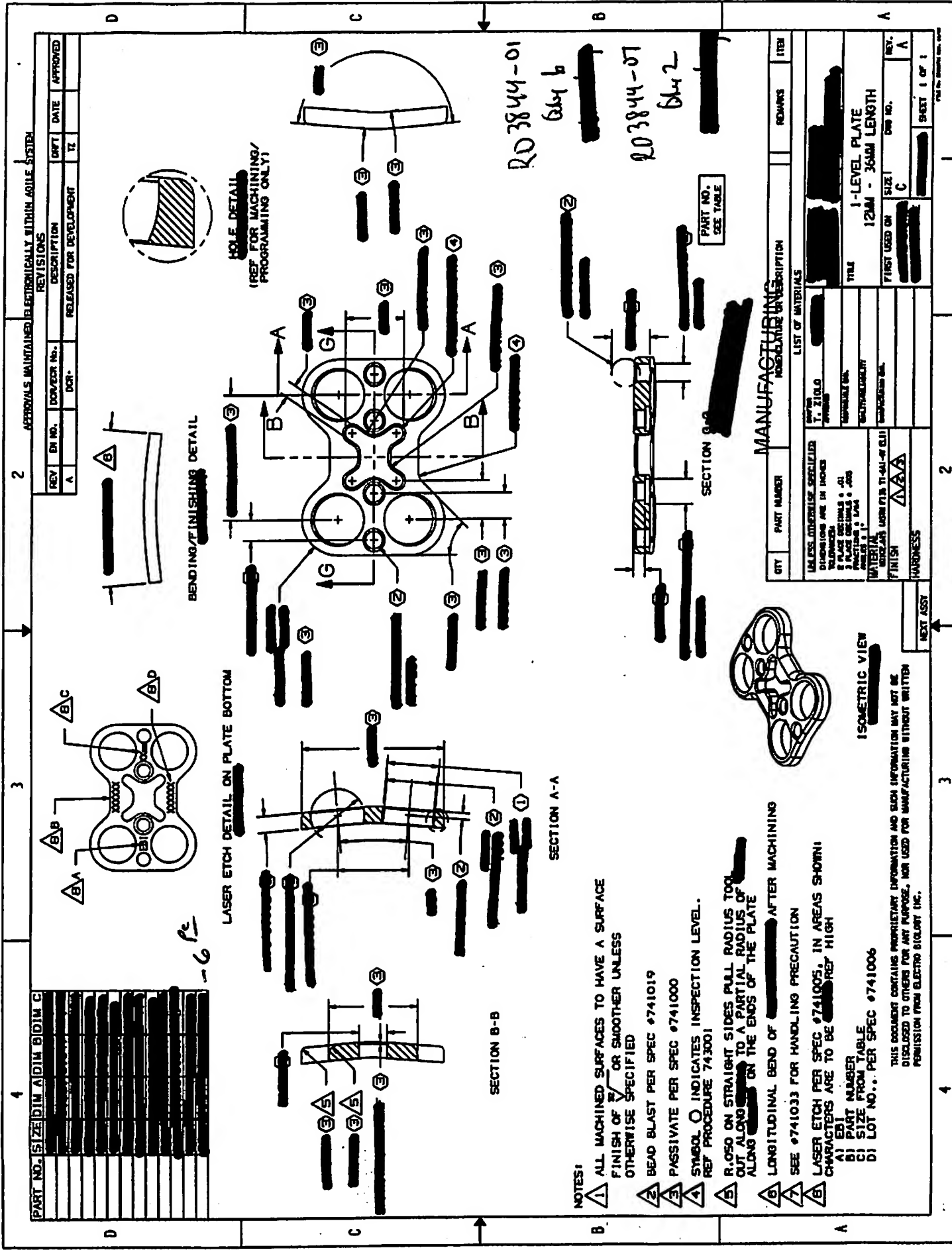
DWG NO. RD-3753

REV. A

SHEET 1 OF 1

QTY 10

2017



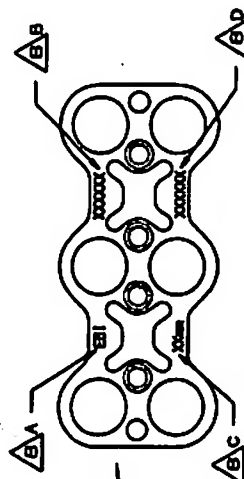
PART NO. SIZE DIM A DIM B DIM C				APPROVALS MAINTAINED ELECTRONICALLY WITHIN ADILE SYSTEM			
REVISIONS				REV. EN NO. DOVER NO. DCR. DATE APPROVED			
A				RELEASED FOR DEVELOPMENT			
				T1			

LIST OF MATERIALS				REMARKS			
ITEM				REMARKS			
1-LEVEL PLATE				12MM - 36MM LENGTH			
TITLE				FIRST USED ON			
SIZE				C			
REV. A				SHEET 1 OF 1			

- NOTES:
- 1 ALL MACHINED SURFACES TO HAVE A SURFACE FINISH OF $\sqrt{}$ OR SMOOTHER UNLESS OTHERWISE SPECIFIED
 - 2 BEAD BLAST PER SPEC #741019
 - 3 PASSIVATE PER SPEC #741000
 - 4 SYMBOL O INDICATES INSPECTION LEVEL. REF PROCEDURE 743001
 - 5 R.050 ON STRAIGHT SIDES PULL RADIUS TOOL CUT ALONG TO A PARTIAL RADIUS OF ALONG ON THE ENDS OF THE PLATE
 - 6 LONGITUDINAL BEND OF AFTER MACHINING
 - 7 SEE #741033 FOR HANDLING PRECAUTION
 - 8 LASER ETCH PER SPEC #741005, IN AREAS SHOWN: A) EBI B) PART NUMBER C) SIZE FROM TABLE D) LOT NO. PER SPEC #741006

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REV	EN NO.	DOC/VER No.	DESCRIPTION	DFT	DATE	APPROVED
A		001-	RELEASED FOR DEVELOPMENT	17		

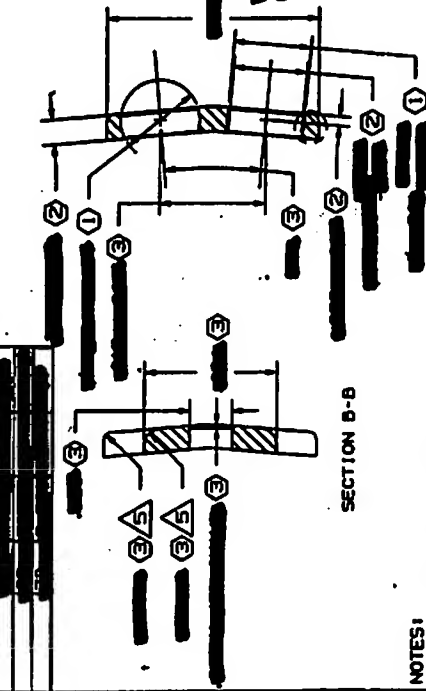


LASER ETCH DETAIL ON PLATE BOTTOM

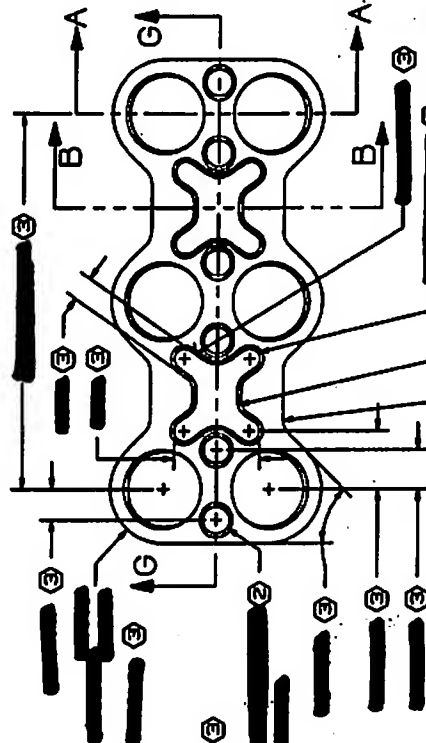


BENDING/FINISHING DETAIL

HOLE DETAIL
**(REFERENCE FOR MACHINING/
PROGRAMMING ONLY)**



SECTION B-B

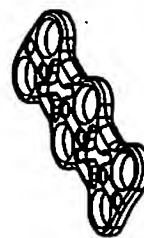


NOTES:

- 1 ALL MACHINED SURFACES TO HAVE A SURFACE FINISH OF $\sqrt{16}$ OR SMOOTHER UNLESS OTHERWISE SPECIFIED
- 2 BEAD BLAST PER SPEC #741019
- 3 PASSIVATE PER SPEC #741000
- 4 SYMBOL \bigcirc INDICATES INSPECTION LEVEL. REF PROCEDURE 743001
- 5 R.050 ON STRAIGHT SIDES PULL RADIUS TOOL OUT ALONG [REDACTED] TO A PARTIAL RADIUS OF [REDACTED] ON THE ENDS OF THE PLATE
- 6 LONGITUDINAL BEND OF [REDACTED] AFTER MACHINING
- 7 SEE #741033 FOR HANDLING PRECAUTION
- 8 LASER ETCH PER SPEC #741005. IN AREAS SHOWN: CHARACTERS ARE TO BE [REDACTED] HIGH
A) EBI
B) PART NUMBER
C) SIZE FROM TABLE

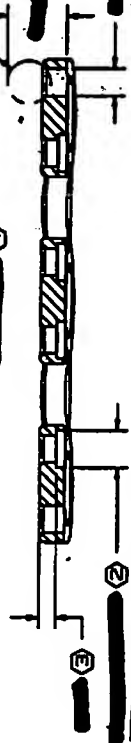
DI LOT NO., PER SPEC 0741006

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




ISOMETRIC VIEW

SECTION 0-0



MANUFACTURING

QTY	PART NUMBER	NUMERICAL CODE OR DESCRIPTION	REMARKS	ITEM
LIST OF MATERIALS				
	LANCE LITERATURE SPECIFIED DIMENSIONS ARE IN INCHES TOLERANCES 3 PLACE DECIMALS ± .001 2 PLACE DECIMALS ± .005 1 PLACE DECIMALS ± .010 ANGLES ± 1°	DRAWN T. ZIGLO APPROVED  MATERIALS MGR.  QUALITY CONTROL  INSPECTION INC.	TITLE 2-LEVEL PLATE 24MM - 70MM LENGTH	
	FINISH 	FIRST USED ON 1-12-71 C	DRG NO. A	REV.
	HARDNESS			SHEET 1 OF 1

PART NO	LENGTH (MM)	ITEM 1	COLOR REF
			LIGHT GREEN
			GRAY
			DARK BLUE
			LIGHT BLUE
			DARK MAGENTA
			BRONZE

RD3844-03

day 44

APPROVALS MAINTAINED ELECTRONICALLY WITHIN ABILE SYSTEM

REV	EN NO.	DO/REV NO.	DESCRIPTION	DRFT	DATE	APPROVED
A		DCR	RELEASED FOR DEVELOPMENT	12		

MANUFACTURING

PART NO. [REDACTED]

THE CERVICAL 4.0MM SCREW ASSY

REV. A

SHEET 1 OF 1

NOTES:

1. LASER ETCH PER SPEC #741005 PRIOR TO ASSEMBLY. IN AREAS SHOWN:
 - A) "EBI"
 - B) LENGTH FROM TABLE
 - C) LOT NO., PER SPEC #741006
2. SNAP ITEM 2 OVER ITEM 1. ROTATE TO RELAXED STATE.

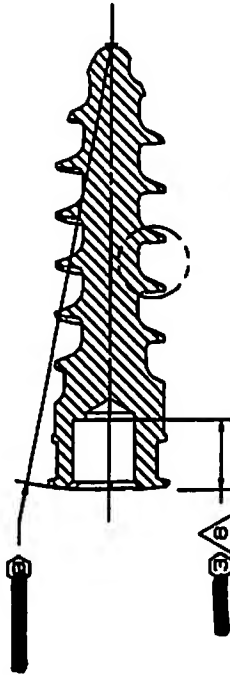
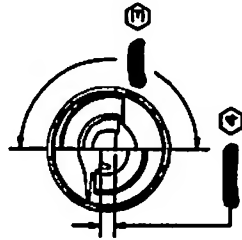
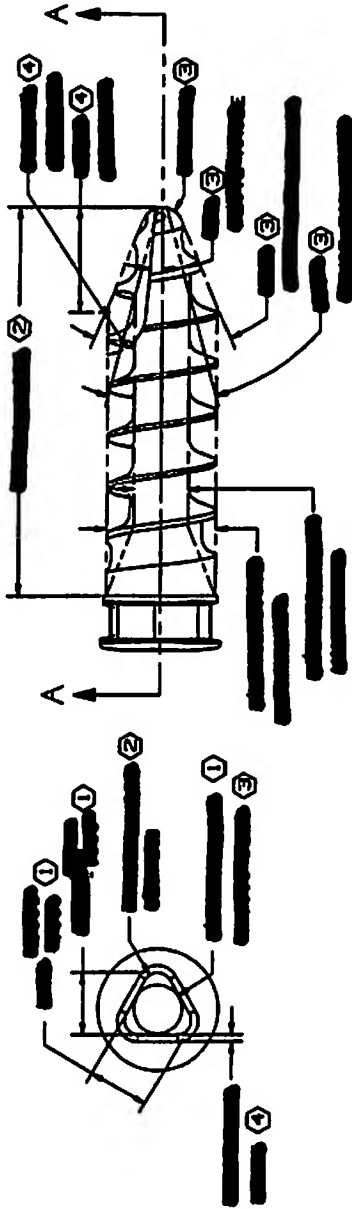
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REV	EN NO.	DESCRIPTION	DATE	APPROVED
A		RELEASED FOR DEVELOPMENT	12	

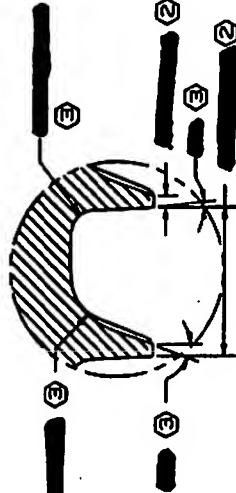
PART NO.	SIZE	LENGTH	DIM A	FINISH
				TITANIUM ANODIZE AS PER EBI SPEC 080077.000 COLOR (LIGHT GREEN)
				PASSIVATE PER EBI SPEC #741000
				TITANIUM ANODIZE AS PER EBI SPEC 080077.000 COLOR (DARK BLUE)
				TITANIUM ANODIZE AS PER EBI SPEC 080077.000 COLOR (LIGHT BLUE)
				TITANIUM ANODIZE AS PER EBI SPEC 080077.000 COLOR (DARK MAGENTA)
				TITANIUM ANODIZE AS PER EBI SPEC 080077.000 COLOR (BRONZE)

203844-04

6/1/84



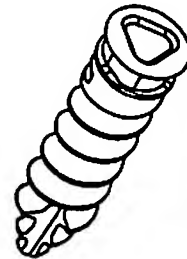
SECTION A-A



THREAD DETAIL

PART NO.
PART

MANUFACTURING



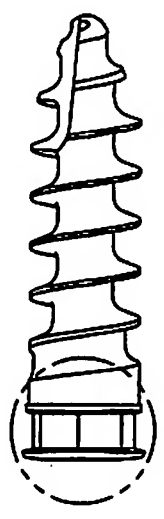
ISOMETRIC VIEW

- NOTES:
- ALL MACHINED SURFACES TO HAVE A SURFACE FINISH OF $\sqrt{10}$ OR SMOOTHER UNLESS OTHERWISE SPECIFIED
 - BEAD BLAST PER SPEC #741019
 - SYMBOL \bigcirc INDICATES INSPECTION LEVEL. REF PROCEDURE 743001
 - INSPECT PARTS USING OVERLAY NUMBER WXXXXX
 - SEE #741033 FOR HANDLING PRECAUTION
 - VISUAL END OF THREAD RUNOUT
 - REF DIMENSIONS FOR MACHINING AND PROGRAMMING ONLY
 - DIMENSION TO THEORETICAL CORNER
 - GEOMETRY SYM \bigcirc ON CENTERLINE

QTY	PART NUMBER	NONCLOSURE OR DESCRIPTION	REMARKS	ITEM
LIST OF MATERIALS				
UNLESS OTHERWISE SPECIFIED				
DIMENSIONS ARE IN INCHES				
TOLERANCES				
FRACTIONS DECIMALS .01				
PLACES DECIMALS .005				
ANGLES .1°				
WATER TIGHT				
FINISH Δ SEE TABLE				
HARDNESS				
NEXT ASSY				
TITLE				
4.0MM CERVICAL SCREW				
FIRST USED ON				
SPINAL SYSTEMS				
CERVICAL PLATE				
REV. A				
SHEET 1 OF 1				

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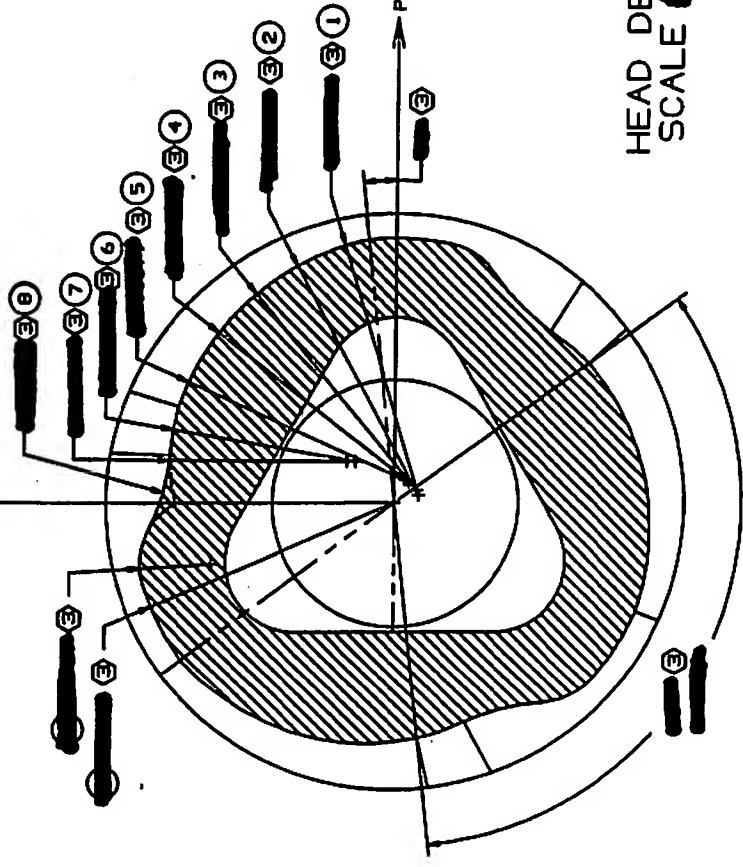
RADIUS NO.	RADIUS X-CENTER Y-CENTER
1	
2	
3	
4	
5	
6	
7	
8	



203844-04
Qty 4244

REVISIONS
SEE SHEET ONE

POSITIVE Y
+

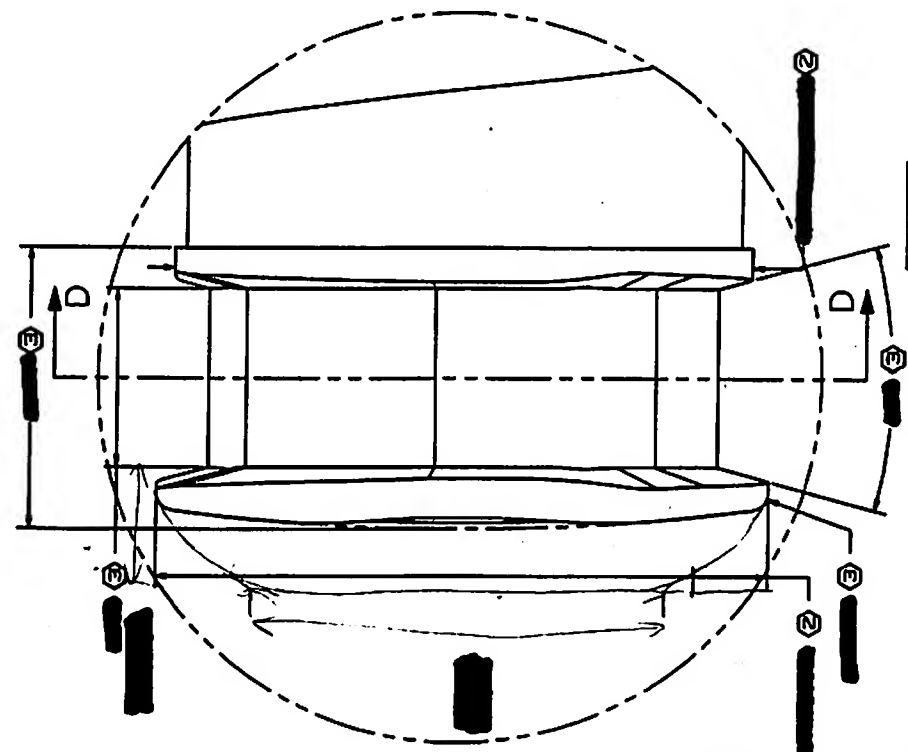


HEAD DETAIL
SCALE

SECTION D-D

NOTES:

- ① CAM PROFILE IS DIMENSIONED FOR ONE OF THE THREE LOBES. LOBES ARE **[REDACTED]** APART.
- ② CAM ORIENTED WITH RESPECT TO THE TRIANGLE DRIVE AS SHOWN.



PART NO.
PART

[REDACTED]
MANUFACTURING

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SIZE	DRW NO.	REV.
C		A

SHEET 2 OF 2

[illegible]

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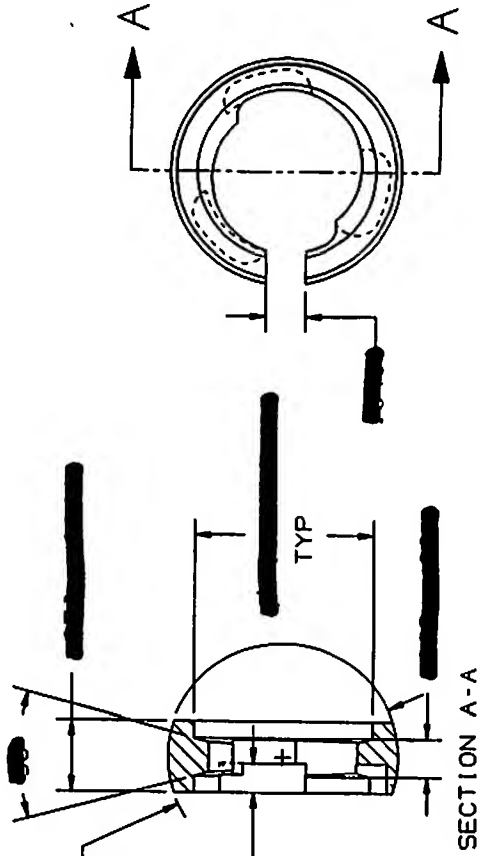
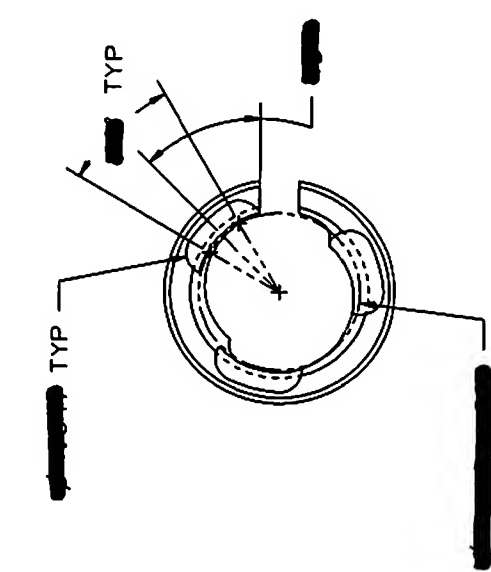
PART NO.
PART

MANUFACTURING		NOMENCLATURE OR DESCRIPTION		REMARKS	ITEM
CITY	PART NUMBER	LIST OF MATERIALS			
BLANKS (OTHERWISE SPECIFIED) DIMENSIONS ARE IN INCHES FOLLOWING: 3 PLATE REELS, 30" 3 PLATE REELS, 40" 3 PLATE REELS, 48" 3 PLATE REELS, 54" 3 PLATE REELS, 60" 3 PLATE REELS, 66" 3 PLATE REELS, 72" 3 PLATE REELS, 78" 3 PLATE REELS, 84" 3 PLATE REELS, 90" 3 PLATE REELS, 96" 3 PLATE REELS, 102" 3 PLATE REELS, 108" 3 PLATE REELS, 114" 3 PLATE REELS, 120" 3 PLATE REELS, 126" 3 PLATE REELS, 132" 3 PLATE REELS, 138" 3 PLATE REELS, 144" 3 PLATE REELS, 150" 3 PLATE REELS, 156" 3 PLATE REELS, 162" 3 PLATE REELS, 168" 3 PLATE REELS, 174" 3 PLATE REELS, 180" 3 PLATE REELS, 186" 3 PLATE REELS, 192" 3 PLATE REELS, 198" 3 PLATE REELS, 204" 3 PLATE REELS, 210" 3 PLATE REELS, 216" 3 PLATE REELS, 222" 3 PLATE REELS, 228" 3 PLATE REELS, 234" 3 PLATE REELS, 240" 3 PLATE REELS, 246" 3 PLATE REELS, 252" 3 PLATE REELS, 258" 3 PLATE REELS, 264" 3 PLATE REELS, 270" 3 PLATE REELS, 276" 3 PLATE REELS, 282" 3 PLATE REELS, 288" 3 PLATE REELS, 294" 3 PLATE REELS, 300" 3 PLATE REELS, 306" 3 PLATE REELS, 312" 3 PLATE REELS, 318" 3 PLATE REELS, 324" 3 PLATE REELS, 330" 3 PLATE REELS, 336" 3 PLATE REELS, 342" 3 PLATE REELS, 348" 3 PLATE REELS, 354" 3 PLATE REELS, 360" 3 PLATE REELS, 366" 3 PLATE REELS, 372" 3 PLATE REELS, 378" 3 PLATE REELS, 384" 3 PLATE REELS, 390" 3 PLATE REELS, 396" 3 PLATE REELS, 402" 3 PLATE REELS, 408" 3 PLATE REELS, 414" 3 PLATE REELS, 420" 3 PLATE REELS, 426" 3 PLATE REELS, 432" 3 PLATE REELS, 438" 3 PLATE REELS, 444" 3 PLATE REELS, 450" 3 PLATE REELS, 456" 3 PLATE REELS, 462" 3 PLATE REELS, 468" 3 PLATE REELS, 474" 3 PLATE REELS, 480" 3 PLATE REELS, 486" 3 PLATE REELS, 492" 3 PLATE REELS, 498" 3 PLATE REELS, 504" 3 PLATE REELS, 510" 3 PLATE REELS, 516" 3 PLATE REELS, 522" 3 PLATE REELS, 528" 3 PLATE REELS, 534" 3 PLATE REELS, 540" 3 PLATE REELS, 546" 3 PLATE REELS, 552" 3 PLATE REELS, 558" 3 PLATE REELS, 564" 3 PLATE REELS, 570" 3 PLATE REELS, 576" 3 PLATE REELS, 582" 3 PLATE REELS, 588" 3 PLATE REELS, 594" 3 PLATE REELS, 600" 3 PLATE REELS, 606" 3 PLATE REELS, 612" 3 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PLATE REELS, 918" 3 PLATE REELS, 924" 3 PLATE REELS, 930" 3 PLATE REELS, 936" 3 PLATE REELS, 942" 3 PLATE REELS, 948" 3 PLATE REELS, 954" 3 PLATE REELS, 960" 3 PLATE REELS, 966" 3 PLATE REELS, 972" 3 PLATE REELS, 978" 3 PLATE REELS, 984" 3 PLATE REELS, 990" 3 PLATE REELS, 996" 3 PLATE REELS, 1002" 3 PLATE REELS, 1008" 3 PLATE REELS, 1014" 3 PLATE REELS, 1020" 3 PLATE REELS, 1026" 3 PLATE REELS, 1032" 3 PLATE REELS, 1038" 3 PLATE REELS, 1044" 3 PLATE REELS, 1050" 3 PLATE REELS, 1056" 3 PLATE REELS, 1062" 3 PLATE REELS, 1068" 3 PLATE REELS, 1074" 3 PLATE REELS, 1080" 3 PLATE REELS, 1086" 3 PLATE REELS, 1092" 3 PLATE REELS, 1098" 3 PLATE REELS, 1104" 3 PLATE REELS, 1110" 3 PLATE REELS, 1116" 3 PLATE REELS, 1122" 3 PLATE REELS, 1128" 3 PLATE REELS, 1134" 3 PLATE REELS, 1140" 3 PLATE REELS, 1146" 3 PLATE REELS, 1152" 3 PLATE REELS, 1158" 3 PLATE REELS, 1164" 3 PLATE REELS, 1170" 3 PLATE REELS, 1176" 3 PLATE REELS, 1182" 3 PLATE REELS, 1188" 3 PLATE REELS, 1194" 3 PLATE REELS, 1200" 3 PLATE 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APPROVALS MAINTAINED ELECTRONICALLY WITHIN AGILE SYSTEM

REVISIONS

REV	EN NO.	DCR/ECR No.	DESCRIPTION	DRFT	DATE	APPROVED
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MANUFACTURING
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1 ALL MACHINED SURFACES TO HAVE A SURFACE FINISH OF $\sqrt{32}$ OR SMOOTHER UNLESS OTHERWISE SPECIFIED

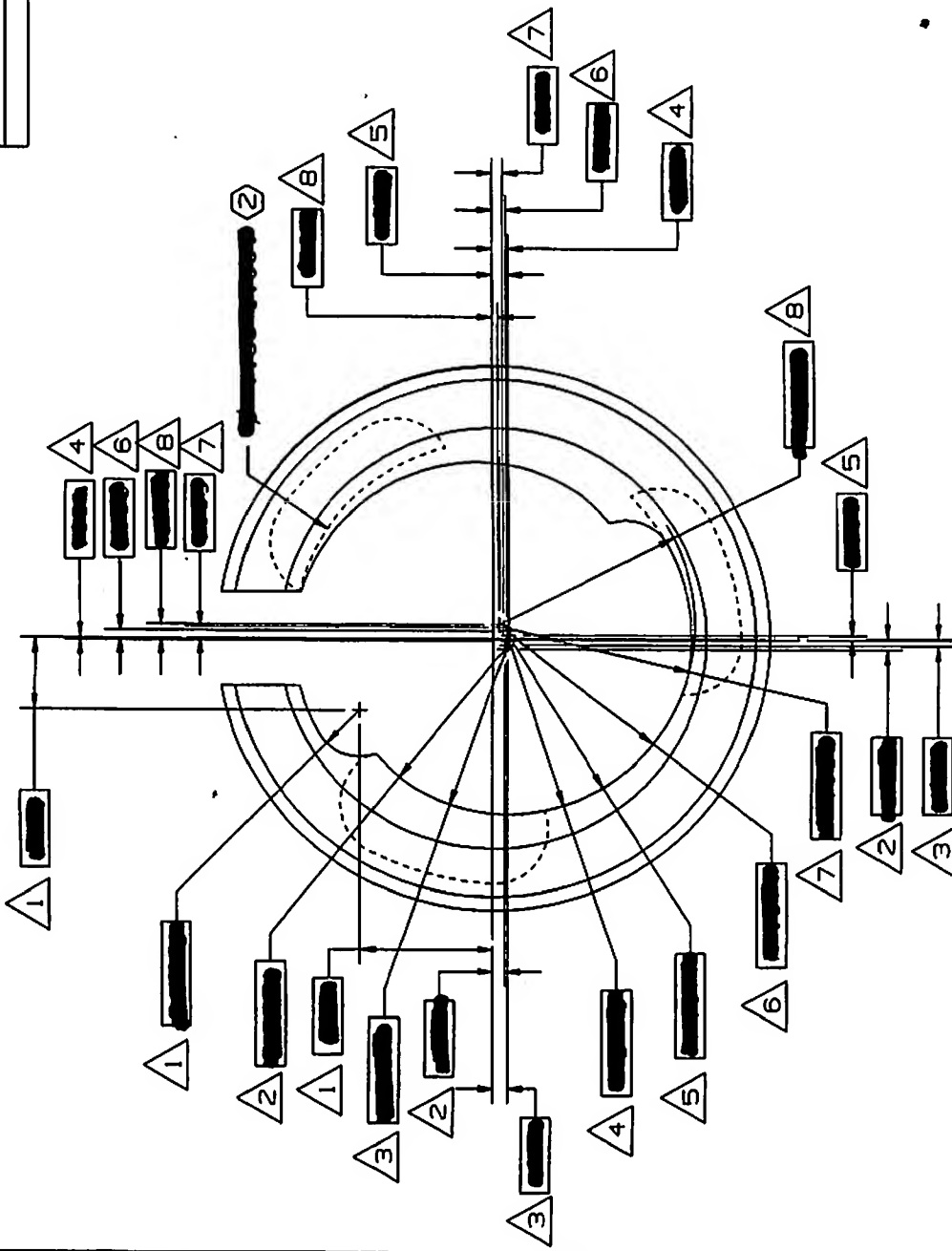
2 MATERIAL TO MEET SPECS 065076.A00 AND ASTM F136

3 PASSIVATE AS PER SPEC 741000

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PART NO.
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NOTES:

- 1 NUMBERS IN TRIANGLES INDICATES WHICH RADIUS CORRESPONDS TO WHICH X AND Y DIMENSIONS
- 2 SYMBOL ○ INDICATES INSPECTION LEVEL REF PROCEDURE 743001